

elf atochem

①
Contains No CBI

ELF ATOCHEM NORTH AMERICA, INC.

900 First Avenue, P.O. Box 1536
King of Prussia, PA 19406-0018

Tel: 215-337-6590
OCT 26 AM 8:23

October 15, 1992

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e)
Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

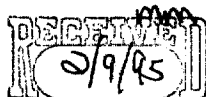
Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed final report on a study to establish skin irritation potential in rabbits to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study report is considered confidential business information of Atochem.

The enclosed study report provides information on a 2-propenoic acid, 2-methyl-methyl ester, polymer with 1,3-butadiene and butyl 2-propenoate. Its CAS number is 33031-74-2.

The title of the enclosed study report is Acute Irritation Tests With DURASTRENGTH® 200 (Lot JLVCP-22R) in Albino Rabbits. This report consists of two studies. The following is a summary of the adverse effects observed in the skin irritation study.

Application of one-half (0.5) gram of test material to the intact and abraded skin of a group of six New Zealand albino rabbits for 24 hours was corrosive to rabbit skin.



②

TSCA CAP
Acrylic Polymer
October 15, 1992
Page Two

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,



C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

DURASTRENGTH® is a registered trade mark.

Industrial **BIO-TEST** *Laboratories, Inc.*

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

REPORT TO

M-48 J

M & T CHEMICALS INC.

✓ ACUTE IRRITATION TESTS WITH
✓ DURASTRENGTH 200 (LOT JLVCP-22R)
✓ IN ALBINO RABBITS

OCTOBER 3, 1974

✓ IBT NO. 601-05601

Industrial **BIO-TEST** *Laboratories, Inc.*

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

October 3, 1974

Mr. Arthur W. Sheldon
Director of Safety and
Environmental Affairs
M & T Chemicals Inc.
Subsidiary of American Can Company
P.O. Box 1104
Rahway, New Jersey 07065

Dear Mr. Sheldon:

Re: IBT No. 601-05601 - Acute Irritation Tests With
Durastrength 200 (Lot JLVCP-22R) in Albino Rabbits

We are submitting herewith our laboratory report prepared
in connection with the above studies.

Very truly yours,

J. C. Calandra

J. C. Calandra
President

JCC:mo

REPORT TO

M & T CHEMICALS INC.

ACUTE IRRITATION TESTS WITH
DURASTRENGTH 200 (LOT JLVCP-22R)
IN ALBINO RABBITS

OCTOBER 3, 1974

IBT NO. 601-05601

I. Introduction

At the request of M & T Chemicals Inc., an eye irritation test and a primary skin irritation test were conducted with a sample identified as Durastrength 200 (Lot JLVCP-22R).

II. Summary

The results of the acute irritation tests conducted with Durastrength 200 (Lot JLVCP-22R) are summarized below:

<u>Test</u>	<u>Rating</u>
Eye Irritation Test - Albino Rabbits	Mildly Irritating (17.2/110.0)
Primary Skin Irritation Test - Albino Rabbits	Extremely Irritating (8.0/8.0)

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

Ronald G. Baker
Ronald G. Baker, B.S.
Assistant Toxicologist
Acute Toxicity

Report approved by:

C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

M. L. Keplinger
M. L. Keplinger, Ph.D.
Manager, Toxicology

slg

III. Results

A. Eye Irritation Test - Albino Rabbits

The results of the eye irritation test are presented in Table I.

TABLE I

Eye Irritation Test - Albino Rabbits

Results

Test Material: Durastrength 200 (Lot JLVCP-22R)

IBT No.: 601-05601

Form Administered: Instillation (100 mg, Undiluted)

Descriptive Rating: Mildly Irritating
(17.2/110.0)

Special Instructions: Unwashed Eyes

Tissue	Rabbit Number	1				7			
		Hour		24 Hours		72 Hours		Days	
Cornea (D-A)	1	0		0		0		0	
Iris		5		0		0		0	
Conjunctiva (R-S-D)		16 (3-2-3), B		2 (1-0-0)		0		0	
Total		21		2		0		0	
Cornea (D-A)	2	0		0		0		0	
Iris		5		0		0		0	
Conjunctiva (R-S-D)		12 (2-1-3)		2 (1-0-0)		0		0	
Total		17		2		0		0	
Cornea (D-A)	3	0		0		0		0	
Iris		5		0		0		0	
Conjunctiva (R-S-D)		16 (3-2-3), B		2 (1-0-0)		0		0	
Total		21		2		0		0	
Cornea (D-A)	4	0		0		0		0	
Iris		5		0		0		0	
Conjunctiva (R-S-D)		12 (2-1-3)		0		0		0	
Total		17		0		0		0	

TABLE I continued

Eye Irritation Test - Albino Rabbits

Results

Test Material: Durastrength 200 (Lot JLVCP-22R)

IBT No.: 601-05601

Tissue	Rabbit Number	1 Hour				24 Hours		72 Hours		7 Days	
		Hour				Hours		Hours		Days	
Cornea (D-A)	5	0				0		0		0	
Iris		5				0		0		0	
Conjunctiva (R-S-D)		12 (2-1-3)				0		0		0	
Total		17				0		0		0	
Cornea (D-A)	6	0				0		0		0	
Iris		0				0		0		0	
Conjunctiva (R-S-D)		10 (1-1-3)				0		0		0	
Total		10				0		0		0	
Averages											
Cornea		0.0				0.0		0.0		0.0	
Iris		4.2				0.0		0.0		0.0	
Conjunctiva		13.0				1.0		0.0		0.0	
Total		17.2				1.0		0.0		0.0	

Conjunctiva:

Cornea: Iris: Iris Score = Value x 5

R = Redness

D = Density

S = Swelling

D = Discharge

Conjunctival Score =

(R+S+D) x 2

Maximum Score = 20

Maximum Score = 80

B. Primary Skin Irritation Test - Albino Rabbits

The results of the primary skin irritation test are presented in
Table II.

TABLE II

Primary Skin Irritation Test - Albino Rabbits

Results

Test Material: Durastrength 200 (Lot JLVCP-22R)
 Form Administered: 500 mg, Undiluted
 Special Instructions: 24-Hour Exposure Period,
 Occluded Sites

IBT No.: 601-05601
 Descriptive Rating: Extremely
 Irritating (8.0/8.0)

Animal Number	Irritation Scores for Abraded Skin Sites At:				Irritation Scores for Intact Skin Sites At:			
	24 Hours		72 Hours		24 Hours		72 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	SCB	-	SCB	-	SCB	-	SCB	-
2	SCB	-	SCB	-	SCB	-	SCB	-
3	SCB	-	SCB	-	SCB	-	SCB	-
4	SCB	-	SCB	-	SCB	-	SCB	-
5	SCB	-	SCB	-	SCB	-	SCB	-
6	SCB	-	SCB	-	SCB	-	SCB	-
Mean	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
Subtotal	16.0				16.0			
Primary Irritation Score = 8.0								

Key: Er. = Erythema

Ed. = Edema

SCB = Second degree chemical burn that will not result in fibrosis. Sites with second degree chemical burns were given maximum irritation scores of 4 for both erythema and edema to obtain a primary irritation score.

IV. Appendix

The detailed investigational procedures employed in these tests are presented in the following pages :

EYE IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used to evaluate the eye irritating properties of the test material. The test method was patterned after that of Draize et al.*

The test material was instilled into the conjunctival sac of the right eye of each rabbit. The left eye of each animal served as a control. At each scoring interval the cornea, iris, and palpebral conjunctiva were examined and graded for irritation and injury according to a standard scoring system*. The maximum possible score at any one examination and scoring period is 110 points, which indicates maximal irritation and damage to all three ocular tissues. Zero score indicates no irritation. The scoring system is presented in Table A. In this scoring system, special emphasis is placed upon irritation or damage to the cornea, while less emphasis is placed upon damage to the iris and conjunctiva.

After the completion of the test, the scores were analyzed, and a descriptive eye irritation rating was assigned to the test material. The criteria used for assignment of the descriptive rating are the frequency, the extent, and the persistence of irritation or damage which occur to the three ocular tissues.

* Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," J. Pharm. & Exp. Ther. 82, 377 (1944).

TABLE A

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	<u>Opacity (D)</u>	
	Opacity - Degree of density (area which is most dense is taken for reading).	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	<u>Area of Cornea Involved (A)</u>	
	One quarter (or less) but not zero.	1
	Greater than one-quarter but less than one-half.	2
	Greater than one-half but less than three-quarters.	3
	Greater than three-quarters, up to whole area.	4
	Score equals $D \times A \times 5$	Total maximum = 80
Iris	<u>Values</u>	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or a combination of any thereof), iris still reacting to light (sluggish reaction is positive).	1
	No reaction to light, hemorrhage, gross destruction (any or all of these).	2
	Score equals value $\times 5$	Total maximum = 10

TABLE A continued

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctiva	<u>Redness (R)</u>	
	Redness (refers to palpebral conjunctiva only). Vessels definitely injected above normal.	1
	More diffuse, deeper crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	<u>Chemosis (S)</u>	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	<u>Discharge (D)</u>	
	Any amount different from normal (does not in- clude small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
Score (R + S + D) x 2		Total maximum = 20

Note: The maximum total score is the sum of all scores obtained from the cornea, iris, and conjunctiva.

The rating is obtained by selecting the maximum mean irritation score at one, 24, or 72 hours after instillation. If the rate of dissipation of injury does not meet the requirements defined for the descriptive rating appropriate for a particular numerical score, the descriptive rating is raised by one or more levels. The rating system is presented in Table B.

TABLE B

Eye Irritation Test - Albino Rabbits

Classification of Test Materials
Based on Eye Irritation Properties

Rating	Range	Definition
Non-Irritating	0.0 - 0.5	To maintain this rating, all scores at the 24-hour reading must be zero; otherwise, increase rating one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this rating, all scores at the 24-hour reading must be zero; otherwise increase rating one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this rating, all scores at the 72-hour reading must be zero; otherwise, increase rating one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this rating, all scores at the 7-day reading must be zero; otherwise, increase rating one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 20. If 7-day mean score is less than or equal to 20 but less than 60% of animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 40. If 7-day mean score is less than or equal to 40 but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained; otherwise, increase rating one level.
Extremely Irritating	Greater than 80.0 - 110.0	

PRIMARY SKIN IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used in the evaluation of the primary skin irritating properties of the test material.

The test procedure was modeled after that of Draize et al.*

Prior to the application of the test material, the hair was clipped from the back and flanks of each rabbit. Two test sites located lateral to the midline of the back approximately ten centimeters apart were selected. One of the two sites was abraded by making four epidermal incisions, two perpendicular to the other two, while the other test site remained intact.

The test material was applied to each of the test sites on each rabbit and occluded with gauze patches which were secured with masking tape. The trunk of each animal was then wrapped with impervious plastic sheeting. The wrap held the patches in position and retarded evaporation of the test material during the 24-hour exposure period.

At the end of 24 hours, the plastic wrappings, patches, and all residual test material were removed. The intact and abraded test sites were examined and scored separately for erythema and edema on a graded scale of 0 to 4. After 72 hours, the sites were again examined and scored.

* Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," J. Pharm. & Exp. Ther. 82, 377 (1944).

In evaluating the average irritation present, the mean scores for erythema and edema of the intact test sites after 24 and 72 hours were added. Similarly, the mean scores for erythema and edema of the abraded test sites after 24 and 72 hours were added. These two values were totaled and divided by four to obtain the mean primary irritation score. The scoring criteria for erythema and edema are shown in the following Table.

The following grading system was used to arrive at a descriptive primary skin irritation rating:

Mean Primary Irritation Score
(Range of Values)

Descriptive Rating

0	Non-Irritating
0.1 - 0.5	Minimally Irritating
0.6 - 1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 - 5.0	Moderately Irritating
5.1 - 6.5	Severely Irritating
6.6 - 8.0	Extremely Irritating

TABLE
Primary Skin Irritation Test - Albino Rabbits
Scoring Criteria for Skin Reactions

Reactions	Description	Score
Erythema	Barely perceptible (Edges of area not defined)	1
	Pale red in color and area definable	2
	Definite red in color and area well-defined	3
	Beet or crimson red in color	4
Edema	Barely perceptible (Edges of area not defined)	1
	Area definable but not raised more than 1 mm	2
	Area well-defined and raised approximately 1 mm	3
	Area raised more than 1 mm	4
Injury In Depth	Escharosis, Necrosis	8
	Maximum Primary Irritation Score =	8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C. H. Farr, PhD, DABT
Manager, Product Safety and Toxicology
Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 20 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12668A



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SEP 15 1995

Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP

CAP

Submission number: 12668A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 1, 2

pages 1, 2, tab

Notes:

Contractor reviewer : LPS

Date: 2/16/95

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHO-1092-12668 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Elf Atochem North

America, Inc.

INFORMATION REQUESTED: FLWP DATE: _____

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TECH)
- 0503 INFO REQUESTED (VOL ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

- 0639 REFER TO CHEMICAL SCREENING
- 0678 CAP NOTICE

OPTIONAL ACTIONS:

- 0401 NO ACTION REPORTED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 LABELING/MSDS (TANGIBLE)
- 0404 PROCESS/ANALYSIS/CHANGE
- 0405 APP/USE DISCONTINUED
- 0406 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

SUB. DATE: 10/15/92 OTS DATE: 10/26/92 CSRAD DATE: 08/09/95

CHEMICAL NAME: Dura strength 200 CAS# 33031-74-2

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCURRENCE/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODCOMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0259 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

USE: _____

TOXICOLOGICAL CONCERN: _____

SPECIES: Rat

ONGOING REVIEW: _____

TRIAGE DATA: NON-CBI INVENTORY: _____

LOW eye irritation

YES (DROP/REFER)

(YES)

MED

NO (CONTINUE)

NO

HIGH chemical irritation

NO (CONTINUE)

IN HUMAN

REFR

10/15/92

12668A

H

Primary dermal irritation in rabbits is of high concern. Extreme irritation was observed following application of the substance to the intact and abraded skin of six New Zealand albino rabbits. Second degree chemical burns were observed in all animals.

L

Primary eye irritation in rabbits is of low concern. Mild irritation was observed following placement of the substance into the conjunctival sac of the right eye of each of six albino rabbits. The following were noted: conjunctival irritation (6/6), clearing by day 3, and iritis (5/6), clearing by day 1.